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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,240

09/09/2003

Ekkehardt Weber

100725-46 / Kreisler 1114

4113

27384

7590

06/21/2006

EXAMINER

JUNG, UNSU

NORRIS, MCLAUGHLIN & MARCUS, PA  
875 THIRD AVENUE  
18TH FLOOR  
NEW YORK, NY 10022

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,240	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Unsu Jung	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 1-46 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-39, drawn to a method for loading paramagnetic particles and isolating and identifying specific target cells contained in body fluids, classified in class 435, subclass 7.23, for example.
  - II. Claims 40 and 43-46, drawn to a kit comprising loaded paramagnetic particles, classified in class 3.24, subclass 9.34, for example.
  - III. Claims 41 and 42, drawn to an incubation buffer, classified in class 562, subclass 584, for example.
3. The inventions are distinct, each from the other because of the following reasons:
4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed

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can be used in a materially different process. The product of Group II can be used to detect and/or isolate non-cellular biological molecules.

5. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. The product of Group III can be used to detect and/or isolate non-cellular biological molecules.

6. Inventions II and III are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the product of Group II includes paramagnetic particles, which is not required by the product of Group III. The product of Group III includes citric acid or sodium or potassium salt, which is not required by the product of Group II. Therefore, the products of Groups II and III have different designs, modes of operation, and effects.

7. Because these inventions are independent or distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent

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subject matter, and searches for one group are not required by the others, restriction for examination purposes as indicated is proper.

***Election of Species within Group I***

8. This application contains claims directed to the following patentably distinct species of the claimed invention I. If Group I is elected, the applicant is required to elect one species from each of the following lists of species. For the species (indicated by letters) having subspecies (indicated by roman numerals) as listed below, applicant is further required to elect one species.

List I: core matrix material (claim 2)

- a. silica
- b. aluminum hydroxide
- c. hydroxyapatite
- d. zirconium hydroxide

List II: paramagnetic material (claim 3)

- a.  $\text{MnSO}_4$
- b.  $\text{FeSO}_4$
- c.  $\text{CoCl}_2$
- d.  $\text{NiSO}_4$

List III: activatable functional groups (claims 4-6, 12, and 13)

- a. --COOH (claims 4-6, 12, and 13)
- b. --SO<sub>3</sub>H (claims 4-6)
- c. --NH<sub>2</sub> (claims 4-6)
- d. --SH (claims 4-6)
- e. CHO (claims 4-6)
- f. --OH (claims 4-6)
- g. acetals (claims 4-6)
- h. epoxy groups (claims 4-6)

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- i. activated derivatives thereof (claims 4-6)

List IV: method of surface attachment of the activatable functional groups (claims 7-11)

- a. attached to the surface of the paramagnetic core matrix via a linker molecule having the activatable functional group at its terminal, wherein the linker molecule comprises the structure --X-tg, wherein X is a C<sub>1-20</sub> group optionally interrupted by one or more heteroatoms and tg is a functional group as defined herein before (claims 7 and 8)
- b. attached to the surface of the paramagnetic core matrix via a coating with a natural polymer carrying the activatable functional groups (claims 9-11)
  - i. homopolymers
  - ii. copolymers derived from monomers having unsaturated carbon chain
- c. attached to the surface of the paramagnetic core matrix via a coating with a synthetic polymer carrying the activatable functional groups (claims 9-11)
  - i. homopolymers
  - ii. copolymers derived from monomers having unsaturated carbon chain

List V: cell types (claims 24 and 25)

- a. metastatic tumor cells
- b. disseminated tumor cells
- c. breast cancer
- d. ovarian cancer
- e. lung carcinoma
- f. melanoma
- g. sarcoma
- h. glioblastoma
- i. other cancers

List VI: first antibody types (claims 26-30)

- a. IgG (claims 26 and 27)
- b. IgM (claims 26 and 27)
- c. IgA (claims 26 and 27)
- d. Isotype (claims 26 and 27)
- e. monoclonal (claims 28-30)

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- i. anti-ESA
- ii. anti-Her2/neu
- iii. anti-melanocyte cell surface antigen
- iv. anti-CD146

List VI: second antibody types (claims 26, 27, 31, and 32)

- a. IgG (claims 26 and 27)
- b. IgM (claims 26 and 27)
- c. IgA (claims 26 and 27)
- d. Isotype (claims 26 and 27)
- e. polyclonal (claims 31 and 32)
  - i. anti-mouse
  - ii. anti-rat
  - iii. anti-rabbit
  - iv. anti-goat
- f. monoclonal (claims 31 and 32)
  - i. anti-mouse
  - ii. anti-rat
  - iii. anti-rabbit
  - iv. anti-goat

The species are independent or distinct because each type of matrix and core material comprises chemically distinct species of material. With respect to types of functional groups, each functional group involve chemically distinct species of molecules and each method of attachment of these functional groups involve using a linker molecule or coating polymer, which are chemically and structurally distinct. Similarly, each type of tumor cells is patentably distinct as well as the specific types of first and second antibodies as their structure, composition, and functional characteristics are distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 14-23, and 33-39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.



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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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